

Amendment and Response

Applicant: William C. Brunnett et al.

Serial No.: 10/776,835

Filed: February 11, 2004

Docket No.: M190.147.101 / PD266.00

Title: HIGH SPEED SURGICAL CUTTING INSTRUMENT

REMARKS

This is responsive to the Non-Final Office Action mailed June 1, 2007. In that Office Action, claims 13-25, 39-43, 60-64, 79-83, 95-99, 111-115, 125-129, and 135-144 were withdrawn from further consideration per Applicant's previous Election. The Combined Declaration and Power of Attorney previously filed on February 11, 2004 was deemed defective. Claims 1-4, 6-8, 12, 26, 30, 31, 33, 34, and 38 were rejected under 35 U.S.C. §102(b) as being anticipated by Etablissements FR '884, French Patent No. 1,166,884 ("FR '884"). Claims 5, 9-11, 27-29, 32, 35-37, 44-59, 65-78, 84-94, 100-110, 116-124, and 130-134 were rejected under 35 U.S.C. §103(a) as being unpatentable over FR '884.

With this Response, claim 6 has been amended; claims 140-144 cancelled; and claim 145 added. Claims 1-5, 7-139, and 145 remain pending in the application and are presented for reconsideration and allowance.

Declaration

A new Declaration in compliance with 37 C.F.R. 1.67(a) is submitted with this Response. Concerns raised by the Examiner with the originally-submitted Declaration have been addressed. As such, acknowledgement that the 37 C.F.R. 1.63 Declaration requirements have been met is respectfully requested.

35 U.S.C. §§102, 103 Rejections

Prior to development of the instruments of the pending application, existing surgical cutting instruments used in cutting tissue at delicate, confined surgical sites were overtly large/straight, could not operate at high cutting speeds (e.g., greater than 50,000 RPM), or both. These inherent drawbacks associated with prior cutting instruments are described in detail at page 1, line 9 – page 4, line 13. A broad goal of providing a high speed surgical cutting instrument has long since existed, but never achieved. Importantly, providing the high rotational speeds desired by surgeons, in many instances with a curved extender, requires much more than simply choosing different materials or constructions as compared to known instruments. If this

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were all that was needed, a plethora of high speed cutting instruments would be available. This is not the case. Instead, extensive inventive efforts are required to improve upon conventional designs.

Prior surgical cutting instruments generally take one of two forms. Either a curved instrument capable of low speed operations only, or a more robust design capable of higher speed cutting but requiring large, inflexible components (e.g., ball bearings). FR '884, relied upon in rejecting the pending claims, represents one of these prior surgical instruments. As a point of reference, a certified translation of FR '884 is provided with this Response. FR '884 is a curved auricular trepan device having an inner wire or stem 1 within a partially curved outer sheath 8. From the illustration of FIG. 1, it is unclear how the tool of FR '884 could function in that the stem 1 is illustrated as curving along a curvature of the outer sheath 8, but yet is not in contact with the sheath 8 except, perhaps, at the distal-most extremity 9. It is respectfully submitted that the co-axially centered stem 1/sheath 8 construction reflected in FIG. 1 is essentially impossible to achieve. Though not explained, it is assumed that the stem 1 freely slides (axially) relative to the sheath 8 at all regions thereof, including along the extremity 9. In this manner, then, the stem 1 can be axially withdrawn from the sheath 8. *FR '884 English Translation, page 2, eighth full paragraph*. If so, it would be impossible for the stem 1 to remain centered relative to the sheath 8 in view of the curvature 8a. Instead, the stem 1 would contact the sheath 8 at discrete points, which in turn would induce a wobbling effect onto the head 3 of the stem 1 as the stem is rotated, especially at high speed rotation. Thus, it is respectfully submitted that FR '884 is non-enabling. In addition, and as described in greater detail below, modifying FR '884 to provide high-speed, long-term operation requires more than simply experimenting with different materials. To the contrary, specific features must be conceived and reduced to practice as done by the inventors of the pending application. Pointedly, one of skill would not understand FR '884 as suggesting or making obvious the high speed surgical cutting instrument described and claimed. As set forth in the concurrently submitted Declaration of William C. Brunnett, the piano wire construction of FR '884 failed at the high speeds contemplated by the present application. Thus, one of skill would not consider the high speed

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surgical cutting instruments of the present application as being made obvious by FR '884. *Brunnett Declaration at Paragraphs 6-8.*

With the above explanation in mind, claim 1 relates to a surgical cutting instrument including an outer tube and an inner wire assembly. The outer tube is maintained by a housing, and defines a lumen within which the inner wire assembly is received. As amended, claim 1 recites that a rotating journal bearing is established between an outer surface of the inner wire assembly and an entity of a length of the inner surface (or lumen) of the outer tube distal the housing. It is respectfully submitted that FR '884 does not teach or reasonably make obvious at least these features. For example, FR '884 discloses that the stem 1 rotates in a rubbing fashion within the extremity 9 of the sheath 8. This rubbing interface is not a rotating journal bearing. Even further, FR '884 requires that the sheath 8 have an increased diameter proximal the extremity 9. FR '884 describes that this enlarged, interior conduit is necessary to allow "free play" between the stem 1 and the sheath 8. *FR '884 English Translation, page 2, seventh full paragraph.* Thus, even if "rubbing" contact between the stem 1 and the extremity 9 is viewed as being a "rotating journal bearing," this contact/bearing does not exist along an entirety of a length of the sheath/outer tube 8. Pointedly, FR '884 teaches away from such an arrangement. Thus, amended claim 1 is allowable over FR '884.

Claims 2-5 and 7-25 depend from claim 1 and thus, for at least the above reasons, are allowable. Other distinctions exist, as described in greater detail below with respect to various other independent claims.

Independent claim 26 relates to a surgical cutting instrument including an outer tube, an inner wire assembly received within a lumen of the outer tube, and a grease lubricant disposed between the outer tube and the inner wire assembly. In this regard, claim 26 requires that the grease lubricant exhibit a dynamic viscosity of not less than the $100 \text{ mm}^2/\text{s}$ at 40°C . In rejecting claim 26 as being obvious over FR '884, the Office Action cites *In re Aller*, 105 USPQ 233 (CCPA 1955) in support of a position that it would have been obvious to provide a lubricant having a viscosity in accordance with claim 26 in that "discovering the optimum or workable ranges involves only routine skill in the art." Applicant respectfully disagrees.

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As a starting point, it is assumed that the Examiner's reference to *In re Aller* derives from MPEP §2144.05 relating to the obviousness of ranges. In this regard, MPEP §2144.05, as well as *In re Aller*, relates to instances in which a claimed range overlaps or lies inside of a range disclosed by the prior art. Relative to the grease lubricant viscosity features of claim 26 and FR '884, no "overlap" exists. That is to say, the analysis set forth in MPEP §2144.05 and *In re Aller* is not relevant to whether claim 26 is made obvious by FR '884 in that the viscosity values of claim 26 are in no way described in, let alone overlapped by, FR '884. In addition, a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of the variable might be characterized as "routine experimentation". *MPEP §2145.05 II.B.* FR '884 clearly does not recognize that lubricant viscosity is a result-effective variable. Rather, FR '884 makes only passing reference to the possibility of decreased rubbing by introduction of a small quantity of a generic lubricant. In light of this failure, selection of lubricant viscosity cannot be characterized as "routine experimentation" in view of FR '884, such that claim 26 is not made obvious by FR '884. Even further, the lubricant dynamic viscosity values of claim 26 is shown as being critical at, for example, page 17, lines 4-13 and page 22, lines 1-3. Under these circumstances, any presumption of obviousness is rebutted. *MPEP §2145.05 III.* For at least the above reasons, it is respectfully submitted that claim 26 is allowable over FR '884.

Claims 27-43 depend from claim 26, and thus, for at least the above reasons are also allowable. Other distinctions exist as described with respect to other independent claims. In addition, claim 33 recites that the hydrodynamic, rotating journal bearing is established along an entirety of a length of the outer tube distal the housing. FR '884 does not teach or reasonably make obvious this additional feature. In particular, due to the enlarged clearance area between the stem 1 and the sheath 8 proximal the extremity 9, the "small quantity of lubricant" disclosed in FR '884 could not establish a hydrodynamic bearing, let alone a hydrodynamic bearing along an entirety of the sheath/outer tube 8. Thus, claim 33 recites additionally allowable subject matter.

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Independent claim 44 relates to a surgical cutting instrument including an outer tube and an inner wire assembly. The inner wire assembly is received within a lumen of the outer tube and is formed of a material exhibiting a fatigue strength of at least 75 Kpsi. In rejecting claim 44, the Office Action cites *In re Aller* in support of a position that it would have been obvious to provide the inner wire/stem 1 of FR '884 with a fatigue strength commensurate with claim 44 as "discovering the optimum or workable ranges involves only routine skill in the art." As described above, *In re Aller*, as well as MPEP §2144.05 that otherwise references *In re Aller*, is limited to circumstances in which a claimed range overlaps or lies inside of a range disclosed in the prior art. FR '884 is void of any reference to a fatigue strength characteristic of the stem/inner wire 1, such that *In re Aller* does not apply. Further, FR '884 does not recognize fatigue strength as being a result-effective variable as is otherwise required before the determination of the optimum or workable ranges of the variable can be characterized as "routine experimentation" in view of FR '884. *MPEP §2144.05 II.B*. Even further, to the extent FR '884 can be viewed as recognizing the result-effective variable nature of fatigue strength, Applicant has shown that the fatigue strength values of claim 44 achieve surprising, unexpected results as described, for example, at page 16, lines 1-8. For at least these reasons, then, it is respectfully submitted that claim 44 is allowable over FR '884.

Claims 45-64 depend from claim 44 and thus, for at least the above reasons, are allowable. Additional distinctions exist as described with respect to various other independent claims.

Independent claim 65 relates to a surgical cutting instrument including an outer tube and an inner wire assembly. The inner wire assembly is received within a lumen of the outer tube and is characterized by a Rockwell Hardness of not less than 50 HRC. In rejecting claim 65 as being obvious over FR '884, the Office Action cites *In re Aller* in support of a position that it would have been obvious to provide the stem/inner wire 1 of FR '884 with a Rockwell Hardness in accordance with claim 65 as "discovering the optimum or workable ranges involves only routine skill in the art." Once again, FR '884 does not provide any hardness values for the inner wire/stem 1, such that *In re Aller* and MPEP §2144.05 do not apply. In addition, FR '884 does

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not recognize hardness as being a result-effective variable. As such, it is improper to characterize modifying the hardness of the inner wire/stem 1 as being “routine experimentation” in view of FR ‘884. *MPEP §2144.05 II.B*. Finally, Applicant has shown that the hardness values of claim 65 provided unexpected results as described, for example, at page 16, lines 22-25 and page 21, lines 10-21. For at least these reasons, it is respectfully submitted that claim 65 is allowable over FR ‘884.

Claims 66-83 depend from claim 65 and thus, for at least the above reasons, are allowable. Additional distinctions exist. For example, FR ‘884 does not teach nor reasonably make obvious coating an exterior surface of the inner wire/stem 1 with a hardened material as otherwise set forth in claim 66, let alone the hardened materials set forth in claims 68 and 69. Thus, claims 66-69 recite additionally allowable subject matter.

Independent claim 84 relates to a surgical cutting instrument including an outer tube and an inner wire assembly. The inner wire assembly is received within a lumen of the outer tube, with the lumen being defined by an inner surface that is highly polished and exhibits a surface roughness of not more than 20 μ inch RMS. In rejecting claim 84 as being obvious over FR ‘884, the Office Action cites *In re Aller* in support of a position that it would have been obvious to provide the sheath/outer tube 8 with a surface roughness commensurate with claim 84 as “discovering the optimum or workable ranges involves only routine skill in the art.” FR ‘884 makes no mention of any surface roughness values, such that no overlap between the surface roughness values and FR ‘884 exist. As such, *In re Aller* (as well as *MPEP §2144.05*) does not apply. In addition, FR ‘884 does not recognize surface roughness as being a result-effective variable, such that it is improper to characterize surface roughness as being “routine experimentation” in view of FR ‘884. Even further, Applicant has shown that the surface roughness values of claim 85 provide unexpected or surprising results as described, for example, at page 15, lines 7-14. For at least these reasons, then, it is respectfully submitted that claim 84 is allowable over FR ‘884.

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Claims 85-99 depend from claim 84, and thus, for at least the above reasons, are allowable. Additional distinctions exist as described with respect to various other independent claims.

Independent claim 100 relates to a surgical instrument including an outer tube and an inner wire assembly. The inner wire assembly is received within a lumen of the outer tube, with the outer tube being maintained by a housing. In this regard, the outer tube has a maximum outer diameter (distal the housing) of not more than 2 mm. Further, a bearing is established between the inner wire assembly and the outer tube, with the instrument configured to allow rotation of the inner wire assembly relative to the outer tube at a speed of 80,000 RPM without failure of the bearing. In contrast, FR '884 does not teach the outer tube/sheath 8 having a maximum outer diameter of not more than 2 mm. In addition, the unconstrained construction of the stem 1 relative to the sheath 8 renders it impossible for the tool of FR '884 to operate at a rotational speed of 80,000 RPM. At these speeds, the rubbing interface between the stem 1 and the extremity 9 of the sheath 8 would quickly disintegrate, and the instrument would fail. For at these reasons, then, it is respectfully submitted that claim 100 is allowable over FR '884.

Claims 101-115 depend from claim 100 and thus, for at least the above reasons, are allowable. In addition, further distinctions exist as described with respect to various other independent claims.

Independent claim 116 relates to a surgical cutting instrument including an outer tube and an inner wire assembly. The inner wire assembly is received within a lumen of the outer tube, with the outer tube exhibiting a stiffness of not less than 15 lbf/inch at a distal end thereof relative to a distal point of interface between the outer tube and a housing otherwise maintaining the outer tube. In rejecting claim 116 as being obvious over FR '884, the Office Action cites *In re Aller* in support of a position that it would have been obvious to provide the outer tube/sheath 8 of FR '884 with a stiffness commensurate with claim 116 as "discovering the optimum or workable ranges involves only routine skill in the art." Applicant respectfully disagrees. FR '884 provides no teaching of any stiffness value or range for the outer tube/sheath 8, such that *In re Aller* (as well as MPEP §2144.05) does not apply. In other words, because no "overlap" exists

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between the stiffness values of claim 116 and the teachings of FR '884, claim 116 cannot be viewed as a mere optimization of FR '884. Along these same lines, FR '884 fails to recognize that stiffness is a result-effective variable such that it is improper to characterize selection of the stiffness values of claim 116 as being "routine experimentation" in view of FR '884. *MPEP* §2144.05 II.B. In addition, Applicant has shown that the stiffness values of claim 116 provide surprising or unexpected results, as described, for example, at page 14, line 18 – page 15, line 6. For at least these reasons, then, it is respectfully submitted that claim 116 is allowable over FR '884.

Claims 117-129 depend from claim 116 and thus, for at least the above reasons, are allowable. Additional distinctions exist as described with respect to various other independent claims.

Independent claim 130 relates to a surgical cutting instrument and recites the various features described above with respect to independent claims 1, 26, 44, 65, 84, 100, and 116. For at least the above reasons, then, it is respectfully submitted that claim 130 is allowable. In addition, in rejecting claim 130, it appears that the Office Action is applying an improper "obvious to try" rationale in support of an obviousness rejection. More particularly, claim 130 recites several feature values, none of which are even touched upon by FR '884. FR '884 does not recognize that any of these parameters are result-effective variables. As a result, one of skill upon viewing FR '884 would be required to vary all parameters set forth in claim 130 and try each of numerous possible choices until possibly arriving at a successful result. Under these circumstances, because FR '884 gives no indication of whether any of these parameters are critical and no direction as to which of many possible choices is likely to be successful, claim 130 cannot be viewed as obvious over FR '884. Simply stated, the "obvious to try" rationale is an improper basis for an obviousness rejection. Thus, claim 130 is allowable over FR '884.

Claims 131-139 depend from claim 130 and thus, for at least the above reasons, are allowable.

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Newly Present Claim

Newly presented claim 145 depends from claim 1 and thus, for at least the above reasons, is allowable. In addition, claim 145 recites that the lumen of the outer tube has a constant diameter in extension from the housing to the distal end. Support for this language is found, for example, in FIG. 1. In contrast, the sheath/outer tube 8 of FR '884 forms a first change in inner diameter immediately distal the cuff/handle 12, a second change in inner diameter immediately distal the cavity 11 (shown at the lead line from "1b"), and a third change in inner diameter in transitioning to the extremity 9. Notably, FR '884 requires this changing diameter to ensure "free play" between the stem/inner wire 1 and the sheath/outer tube 8 as well as to allow the stem/inner wire 1 to absorb certain centering differences. *FR '884 English Translation at paragraph bridging page 1 and page 2.* Thus, claim 145 recites additionally allowable subject matter.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1-5, 7-139, and 145 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1-5, 7-139, and 145 are respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this communication should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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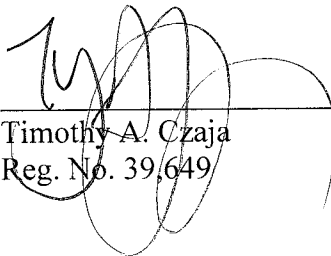
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Respectfully submitted,

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By their attorneys,

Date: October 1, 2007
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